IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 10 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY SUPPORTING DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this reply brief in further support of their motion to exclude certain of Dr. Daniel Elliott's general opinions.

Plaintiffs claim that Ethicon's Wave 10 brief merely "reiterate[s] nearly verbatim arguments already asserted in previous Waves of the MDL." Pl's Resp. (Doc. 8247), p. 1. If Plaintiffs genuinely believed that to be true, they would have simply incorporated by reference their prior wave responses rather than filing an 18-page brief responding to the new—and significant—arguments that Ethicon has raised.

In fact, Ethicon's Wave 10 brief is much different because, after prior wave briefing, Dr. Elliott has published his "2019 Article," that refutes many of the assertions he has made in his expert reports. *See* Ex. G to Doc. 8080, Brian J. Linder & Daniel S. Elliott, *Synthetic Midurethral Slings*, 46 Urol. Clin. N. Am. 17, 21 (2019). By suggesting that Ethicon is merely rehashing old arguments, Plaintiffs apparently hope that the Court will not recognize this significant development.

Plaintiffs go to great—albeit specious—lengths to attempt to distance Dr. Elliott from his 2019 Article, even going so far as to suggest that the content set forth in the article should not be attributed to him because he "was only a corresponding author." Pl's Resp. (Doc. 8247), p. 3. That fanciful argument aside, the lynchpin of Plaintiffs' response is that the article "actually corroborates Dr. Elliott's expert reports" on the basis that the article's references to type I mesh supposedly does not encompass the Prolene mesh used in TVT and similar devices. *Id.* at 3-6 As set forth below, Plaintiffs' position is wholly disingenuous.

Throughout his 2019 Article, Dr. Elliott touts the benefits of type I mesh for the surgical treatment of SUI, calling it "ideal," the "standard of care," a "great advance," and "extensively researched." Ex. G to Doc. 8080, pp. 17, 21. Incredibly, Plaintiffs assert that "the 2019 article defines 'type I' or the 'ideal mesh' as large pore, and monofilament, while Dr. Elliott has explained that TVT mesh is heavyweight and small pore—**what the article defines as "type III."** Pl's Resp. (Doc. 8247), p. 6. Plaintiff's assertion that Dr. Elliott's 2019 Article categorizes TVT mesh as type III mesh is blatantly false.

In the 2019 Article, Dr. Elliott states as follows:

> Currently, the ideal mesh should be large pore (>75μm) and monofilament (**type I**), to allow for the body's immune responses to penetrate the interstices and collagen fiber incorporation. Previous use of smaller pore size meshes (**type III**) was associated with mesh encapsulation and high rates of mesh exposure and infection.

Ex. G to Doc. 8080, p. 19 (emphasis added, footnote omitted). In a footnote after the last sentence above, Dr. Elliott cites to a Consensus Statement of the European Urology Association and the European Urogynaecological Association, filed herewith as Exhibit A. *Id.* at 19 n.12.

That Consensus Statement defines type I mesh as being "monofilament with the pore size being >75 microns" and type III mesh as having a pore size of less than 10 microns. Ex. A

hereto, pp. 4-5. Originally classified by Dr. P.K. Amid, this definition is widely used within the industry. *See* Ex. B hereto, P.K. Amid, *Classification of biomaterials and their related complications in abdominal wall hernia surgery*, Hernia, 1 (1997), pp. 15-21; Ex. C hereto, Donald R. Ostergard, *Vaginal mesh grafts and the Food and Drug Administration*, Int'l Urogynecol J. 10:1181 (2010) (article by one of Plaintiffs' experts referencing these classifications).

It is beyond any genuine dispute that the Prolene mesh in TVT and Ethicon's similar devices is type I mesh. Indeed, Amid's article explicitly identifies "Prolene" as an example of type I mesh. Ex. B hereto, Amid at 15. In fact, not only is the TVT mesh's pore size greater than 75 microns, it is **1,379** microns. Ex. D hereto, Pamela A. Moalli, et al., *Tensile properties of five commonly used mid-urethral slings relative to the TVT*, Int'l Urogynecol J. 19:663, 657 tab. 1 (2010).

In other words, TVT mesh's pore size is 1,369 microns more than the classification of type III mesh. This is the first instance in which Ethicon is aware that Plaintiffs have suggested that TVT mesh is anything other than type I mesh. In fact, in discussing mesh classifications, one of Plaintiffs' own experts, Donald Ostergard, has stated that "[t]he TVT® mesh is monofilament with very large pores and a limited amount of interstices." Ex. C, Ostergard at 5.

At no point does Dr. Elliott's 2019 Article suggest that its references to type I or type III mesh are any different than the Amid classifications that are used throughout the industry. Nor did Plaintiffs submit an affidavit from Dr. Elliott stating as such. Accordingly, the Court should reject Plaintiffs' spurious suggestion that Dr. Elliott's 2019 Article's references to type I mesh was not intended to include Prolene.

This is not merely an issue for cross-examination, as Plaintiffs suggest. Instead, Dr. Elliott's 2019 Article presents a very serious issue in which a paid expert is making assertions in this litigation that are directly contradicted by the assertions that he is simultaneously making in academic literature.

Indeed, in reviewing Dr. Elliott's 2019 Article, the Court may ask one simple question: Does this article appear to be written by the same person who, in this litigation, has testified that "**all"** polypropylene mid-urethral mesh slings are "unsafe"? Ex. H to Doc. 8080, 9/26/15 Dep. 143:11-14, 144:16-18, 285:22.

The Supreme Court has made clear that it is incumbent on a district court to exercise its gatekeeping role so as to ensure that a witness has not "employed less intellectual rigor in forming his opinion as an expert witness than he employs when writing studies in his field"—not "punt" the issue for the jury to consider. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). For these reasons, the Court should limit Dr. Elliott's general causation opinions consistent with the relief sought by Ethicon in its motion and initial brief.

Respectfully submitted,

/s/ William M. Gage
William M. Gage (MS Bar No. 8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

Susan M. Robinson (W. Va. Bar No. 5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

Counsel for Defendants

CERTIFICATE OF SERVICE

I certify that on this date I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
William M. Gage

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